IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA, Plaintiff, v. DELTEX PHARMACEUTICALS, INC., a corporation, and KABIR AHMED and MOHIDUR R. KHAN, individuals, Defendants.	Civil Action No. H-10-5178 CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction ("Complaint") against Deltex Pharmaceuticals, Inc., a corporation, and Kabir Ahmed and Mohidur R. Khan, individuals (collectively, "Defendants"), and Defendants, solely for the purposes of settlement of this case and without admitting or denying the allegations in the Complaint, having appeared and having consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–99a (the "Act").

3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(d), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

4. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1) (hereinafter, "drug" or "drugs"), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that they have been manufactured, processed, packed, labeled, held, and distributed in violation of current good manufacturing practice ("CGMP"), 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211.

5. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration within the meaning of 21 U.S.C. § 351(a)(2)(B) of drugs after shipment of one or more of their components in interstate commerce.

6. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce drugs that are misbranded under 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use, and under 21 U.S.C. § 352(c), in that their labeling fails to display required information prominently and in understandable terms.

7. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment of one or more of their components in

interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 352(c) and (f)(1).

8. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing any drug unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in compliance with CGMP, 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211;

B. Defendants retain, at Defendants' expense, an independent person or persons (the "CGMP expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to inspect Defendants' drug manufacturing facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity and qualifications of the CGMP expert as soon as they retain such expert;

C. The CGMP expert performs a comprehensive inspection of Defendants' facilities and the methods and controls used to manufacture, process, pack, label, hold, and

distribute drugs to determine whether they are in compliance with CGMP. This inspection shall include, at a minimum, the following:

(1) An evaluation as to whether the Defendants have established a comprehensive written quality assurance ("QA") and quality control ("QC") program ("QA/QC program") that is adequate to ensure continuous compliance with applicable laws and regulations.

(2) A determination that the QA/QC program, at a minimum:

a. Addresses all facets of compliance monitoring and trend analyses, and internal audit procedures;

b. Includes procedures to ensure that the Defendants thoroughly investigate any unexplained discrepancy or the failure of a batch of drug or its components to meet any of the product's or component's specifications, including the extension of such investigation to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy;

c. Establishes mechanisms to ensure that written standard operating procedures ("SOPs") specifying the responsibilities and procedures applicable to QA or QC personnel are followed;

d. Includes written SOPs necessary to ensure that all facets of compliance monitoring are reviewed and controlled by QA personnel; and

e. Includes written SOPs to ensure that (i) Defendants' QA personnel are promptly notified in writing of deviations and/or problems that could affect the safety, identity, strength, quality, and purity of any drug; (ii) Defendants' QA personnel

participate in or monitor the implementation and verification of corrective actions to prevent future occurrences of such deviations and/or problems; and (iii) there are systems to ensure that such written SOPs are continuously followed.

D. The CGMP expert certifies in writing to FDA that:

(1) he or she has inspected Defendants' facilities, methods, processes, and controls;

(2) all CGMP deviations brought to Defendants' attention since 2003 by FDA, the CGMP expert, or any other source have been corrected; and

(3) such facilities, methods, processes, and controls are in compliance with the requirements of CGMP. As part of this certification, the CGMP expert shall include a full and complete detailed report of the results of his or her inspection;

E. Defendants cease manufacturing, processing, packing, labeling, holding, and distributing all new drugs, as defined in 21 U.S.C. § 321(p), that lack an approved new drug application or abbreviated new drug application under 21 U.S.C. § 355, unless the drug is exempt from the approval requirements pursuant to an effective exemption under 21 U.S.C. § 355(i), or unless the drug is an over-the-counter ("OTC") drug that is made and labeled in strict conformity with all of the requirements set forth in an applicable FDA OTC drug monograph, 21 C.F.R. Part 330. Such drugs shall specifically include, but not be limited to, the following:

(1) Bromphenex DM

(2) ED-APAP Children's

(3) EndaCof-AC Syrup

(4) EndaCof-C Liquid

(5) EndaCof-DC Liquid

(6) ExeClear-C Syrup

(7) Myci-GC

(8) Z-Tuss AC

(9) Z-Xtra;

F. Defendants cease manufacturing, processing, packing, labeling, holding, and distributing all drugs that are misbranded under 21 U.S.C. §§ 352(c) or (f)(1), including, but not limited to, the drugs listed in the preceding subparagraph;

G. Defendants report to FDA in writing, confirmed in writing by their independent expert(s), the actions they have taken to:

(1) correct the CGMP deviations brought to Defendants' attention since 2003 by FDA, the CGMP expert, and any other source;

(2) ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are operated and will be continuously administered in conformity with CGMP;

(3) bring their products into compliance with the drug approval provisions of the Act; and

(4) ensure their products have adequate directions for use;

H. Defendants recall from their customers, and further advise their customers to recall to the retail level, all unapproved new drugs that Defendants have manufactured, processed, packed, labeled, held, or distributed on or after October 31, 2008, and destroy the

drugs recalled from Defendants' customers in accordance with the procedures provided in paragraph 11, and under FDA's supervision in a manner preapproved in writing by FDA;

I. FDA representatives, as FDA deems necessary, inspect Defendants' facilities to determine whether the requirements of this Decree have been met, and whether Defendants' facilities are operating in conformity with CGMP, the Act, and its implementing regulations; and

J. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs 8(A)–(H). If Defendants do not appear to be in compliance, FDA shall provide Defendants a written notice of the deficiencies. In no circumstance will FDA's silence be construed as a substitute for written notification.

9. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Introducing or delivering for introduction into interstate commerce any drug, unless and until:

(1) an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355 is in effect for such drug; or

(2) an investigational new drug application filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312 is in effect for such drug and the drug is distributed and used solely for the purpose of conducting clinical investigations in strict accordance with the investigational new drug application; or

(3) such drug is an OTC drug and conforms strictly to all of the requirements set forth in an applicable OTC drug monograph, 21 C.F.R. Part 330;

B. Introducing or delivering for introduction into interstate commerce any drug that is:

(1) adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); or

(2) misbranded within the meaning of 21 U.S.C. §§ 352(c) or (f)(1); and

C. While any drug is held for sale after shipment of one or more components in interstate commerce:

(1) causing the adulteration of such drug within the meaning of 21 U.S.C. § 351(a)(2)(B); or

(2) causing the misbranding of such drug within the meaning of 21 U.S.C. §§ 352(c) or (f)(1).

10. Before Defendants may commence manufacturing or distributing any drug or continue the manufacture or distribution of any previously distributed drug, Defendants shall first notify FDA in writing of their intention to do so, and shall also do the following:

A. For any drug that is not manufactured and labeled in strict conformance with an applicable OTC monograph under the terms of subparagraph 10(B), Defendants shall demonstrate to FDA that the drug is the subject of either (1) an approved application filed under 21 U.S.C. § 355(a) or § 355(j), or (2) an effective investigational new drug application filed under 21 U.S.C. § 355(i). In no event may Defendants distribute a drug product that is not the subject of an approved application under 21 U.S.C. §§ 355(a) or (j), or the subject of an effective

investigational new drug application under 21 U.S.C. § 355(i), which must explicitly authorize manufacture of the drug at Defendants' facility;

B. If the product purports to be an OTC monograph drug as described in paragraph 9(A)(3), Defendants may not distribute such drug unless and until:

(1) Defendants retain, at Defendants' expense, an independent person or persons (the "drug monograph expert"), who is without any personal or financial ties (other than the agreement) to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to review the labeling of Defendants' OTC drug(s) to determine whether such product complies with the applicable OTC drug monograph and other labeling requirements of the Act and FDA regulations. Defendants shall notify FDA in writing of the identity and qualifications of the drug monograph expert as soon as they obtain such expert;

(2) The drug monograph expert performs a comprehensive review of the OTC drug and the drug's proposed labeling to determine whether the product strictly conforms to an applicable FDA OTC monograph and all labeling requirements, including 21 C.F.R. Part 201, and that the OTC drug is not otherwise misbranded;

(3) The drug monograph expert certifies in writing to FDA that: (a) he or she has reviewed the OTC drug and its labeling; (b) the OTC drug and its labeling conform to the requirements of an OTC drug monograph and all applicable labeling requirements, including 21 C.F.R. Part 201; and (c) the OTC drug is not otherwise adulterated or misbranded. As part of this certification, the drug monograph expert shall attach the labeling he or she has received to a full and complete detailed report of the results of his or her review, including, but not limited to,

identifying the labeling he or she reviewed and references to the OTC monograph and labeling regulations addressed in the process of conducting the labeling review;

(4) Defendants have provided to FDA any additional information requested by FDA after FDA's review of the drug monograph expert's certification pursuant to subparagraph 10(B)(3); and

(5) FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs 10(B)(1)–(4), the Act, and the applicable regulations related to OTC drug products. In no circumstance may FDA's silence be construed as a substitute for written notification. If FDA finds, after issuance of this notification, that Defendants are not in compliance with subparagraphs 10(B)(1)–(4), the Act, or applicable regulations related to OTC drug products, Defendants, upon notification from FDA, shall immediately take whatever action that FDA specifies. For submissions concerning the products Dexphen w/C Liquid, ED A-HIST Liquid, Ed ChlorPed Ped. Drops, EndaCof-DC Liquid, and Z-Tuss AC, FDA will notify Defendants as to whether Defendants appear to be in compliance within forty-five (45) business days of receipt of the monograph expert's initial certification as set forth in subparagraph 10(B)(3) or receipt of any information requested by FDA pursuant to subparagraph 10(B)(4).

11. Within thirty (30) calendar days of entry of this Decree, Defendants shall, under FDA observation and pursuant to a plan approved in writing by FDA, destroy: (A) all unapproved new drugs in Defendants' possession, custody and/or control; (B) all drugs in Defendants' possession, custody, and/or control that are adulterated because they were not manufactured, processed, packed, labeled, held, and/or distributed in accordance with CGMP;

and (C) all drugs in Defendants' possession, custody, and/or control that are misbranded. Defendants shall reimburse FDA for the supervision of the destruction at the rates set forth in paragraph 14 of this Decree. Defendants shall not dispose of any drugs in a manner contrary to any federal, state, or local laws, including but not limited to, the National Environmental Policy Act of 1969. Paragraph 11 shall not apply to drugs that are held for the sole purpose of being stability samples or retains, and such drugs shall not be distributed or sold.

12. After Defendants have complied with paragraphs 8(A)–(H) and FDA has notified them pursuant to paragraph 8(J), Defendants shall retain an independent person or persons (hereinafter, "auditor") who shall meet the criteria described in paragraph 8(B) to conduct audit inspections of their drug manufacturing operations no less frequently than once every six (6) months for a period of no less than three (3) years, and no less frequently than once every year for two (2) years thereafter. If Defendants choose, the auditor may be the same person or persons retained as the CGMP expert in paragraph 8(B).

A. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance with CGMP and identifying any deviations from CGMP ("audit report observations"). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the audit inspection(s) is completed. In addition, Defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any observations indicating that Defendants are not in compliance with CGMP, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the deviations will take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule"). The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance will FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

13. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' place(s) of business and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted ready access to Defendants' place(s) of business including, but not limited to, all buildings, equipment, finished and unfinished materials and products, containers, labeling, and other promotional material

therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, labeling, and other promotional material; and to examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all of Defendants' drugs, including components, in order to ensure continuing compliance with the terms of this Decree. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374. In addition, in order to ensure Defendants' compliance with this Decree, Plaintiff and FDA are authorized to monitor Defendants' compliance with this Decree by all lawful means, without the necessity of prior notice.

14. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date of entry of this Decree, these rates are: $85.49 per hour or fraction thereof per representative for inspection and investigative work; $102.49 per hour or fraction thereof per representative for laboratory and analytical work; $0.55 per mile for travel expenses by automobile, government rate or the equivalent for travel by air; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court. In addition, should Plaintiff bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall pay all attorneys' fees and costs, travel expenses incurred by attorneys

and witnesses, expert witness fees, investigational and analytical expenses, and court costs incurred by Plaintiff in bringing such an action.

15. Within ten (10) calendar days of the entry of this Decree, Defendants shall post a copy of this Decree on a bulletin board in a common area at Deltex's facility located at 1700 Bamore Road, Rosenberg, Texas, and at any other location at which Defendants conduct business, and shall ensure that the Decree remains posted at each location for as long as the Decree remains in effect.

16. Within ten (10) calendar days of the date of entry of this Decree, Defendants shall provide a copy of the Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, customers, and any and all persons in active concert or participation with any of them (collectively referred to as "Associated Persons"). Within thirty (30) calendar days of the date of entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Decree pursuant to this paragraph.

17. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within ten (10) calendar days of each time any of the Defendants becomes associated with any such additional Associated Person, Defendants shall provide to the District Director, FDA Dallas District Office, an affidavit stating the fact and

manner of their compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) calendar days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA. Defendants are not required, pursuant to paragraph 17, to provide new customers a copy of this Decree.

18. Defendants shall notify FDA, in writing at least fifteen (15) calendar days before any change in ownership, character, or name of any of their businesses, including incorporation, reorganization, bankruptcy, assignment, sale resulting in the emergence of a successor business or corporation, or any other change in the structure or identity of Deltex Pharmaceuticals, Inc., or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least ten (10) calendar days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

19. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report or data prepared or submitted by Defendants, the CGMP expert, the drug monograph expert, the auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, the Act, or its implementing regulations, have manufactured or distributed unapproved new drugs or adulterated or misbranded drugs, or that additional corrective actions are necessary to achieve compliance with this Decree, CGMP,

the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease all manufacturing, processing, packing, labeling, holding, and/or distributing any or all drug(s);

B. Recall, at Defendants' own expense, any drug that is adulterated, misbranded, unapproved, or otherwise in violation of this Decree, CGMP, the Act, or its implementing regulations;

C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

D. Submit additional reports or information to FDA;

E. Issue a safety alert; and/or

F. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, CGMP, the Act, or its implementing regulations.

20. Upon receipt of any order issued by FDA pursuant to paragraph 19, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 19 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, CGMP, the Act, and its implementing regulations, and that Defendants may, therefore, resume operations.

21. Defendants shall pay all costs of such recalls and corrective actions, including the costs of FDA supervision, inspections, investigations, analyses, examinations, reviews, travel, and subsistence expenses to implement recalls and other corrective actions, at the rates specified in paragraph 14 of this Decree. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

22. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on motion of the United States in this proceeding, Defendants shall pay to the United States of America: two thousand five hundred dollars ($2,500) in liquidated damages for each calendar day such violation continues; an additional sum of five hundred dollars ($500) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree; and an additional sum equal to twice the retail value of each shipment of an unapproved new drug or adulterated or misbranded drug, in liquidated damages for each such unlawful shipment. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

23. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

24. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be addressed to the District Director, FDA Dallas District Office, 4040 North Central Expressway, Suite 300, Dallas, Texas 75204.

25. No sooner than seven (7) years after entry of this Decree, Defendants may petition this Court for an order dissolving this Decree. If Defendants have maintained, to FDA's satisfaction, a state of continuous compliance with this Decree, the Act, and all applicable regulations for seven (7) years preceding Defendants' petition, the government will not oppose such petition.

26. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this 14th day of January, 2010.

UNITED STATES DISTRICT JUDGE

Entry consented to:

For Defendants

KABIR AHMED
Individually and on behalf of
DELTEX PHARMACEUTICALS,
INC., as its President

MOHIDUR R. KHAN
Individually and on behalf of
DELTEX PHARMACEUTICALS,
INC., as its Vice President

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Silver Spring, Maryland 20993

Entry consented to:

For Defendants

KABIR AHMED
Individually and on behalf of
DELTEX PHARMACEUTICALS,
INC., as its President

MOHIDUR R. KHAN
Individually and on behalf of
DELTEX PHARMACEUTICALS,
INC., as its Vice President

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Individually and on behalf of
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